CLAIMS:

1. A purified and isolated peptide, pE2, comprising an amino acid sequence identified by SEQ ID NO: 2, or a homologous sequence, fragment or analog thereof having antigenic properties similar to the pE2 peptide.

2. A recombinant fusion protein comprising a heterologous amino acid sequence fused to the amino acid sequence, as defined in Claim 1.

3. A recombinant fusion protein according to Claim 2, characterized in that the heterologous amino acid sequence codes for glutathione S-transferase.

4. A method of generating the pE2 peptide, as defined in Claim 1, either by chemical synthesis or recombinant DNA expression.

5. A purified and isolated nucleic acid molecule, E2, comprising a DNA sequence identified by SEQ ID NO: 1, or a homologous sequence or fragment thereof.

6. A purified and isolated nucleic acid molecule, comprising a DNA sequence which encodes the pE2 peptide, as defined in Claim 1.

7. A purified and isolated nucleic acid molecule, comprising the sequence identified by SEQ ID NO: 3.

8. A vector containing the nucleic acid molecule according to Claim 5 or 6, characterized in that the vector is capable of expressing the nucleic acid molecule upon introduction into an appropriate host cell or microorganism.

9. A vector according to Claim 8, characterized in that the vector is a plasmid.

10. A vector according to Claim 8, characterized in that the host cell is a eukaryotic cell.

11. A vector according to Claim 10, characterized in that the eukaryotic cell is E. Coli.

12. A host cell or microorganism transformed with the vector as defined in any one of Claims 8 to 11.

13. A method for generating the peptide or protein, as defined in any one of Claims 1 to 3, comprising inserting a nucleic acid molecule that encodes the peptide or protein into a vector construct that it is capable of being expressed in an appropriate host cell or microorganism, transforming a host cell or microorganism with the vector construct, culturing the transformed host cell or microorganism, and isolating and purifying the resulting peptide or protein product.

14. A method for producing a purified antibody against the pE2 peptide, as defined in any one of Claims 1 to 3, comprising injecting into a non-human mammalian host, an immunologically effective amount of the pE2 peptide, and isolating and purifying the antibody produced.

15. A purified antibody, or fragment thereof, which has been raised against the pE2 peptide, as defined in any one of Claims 1 to 3.

16. A vaccine composition for immunizing an individual against infection from hepatitis E virus (HEV) comprising the pE2 peptide, as defined in any one of Claims 1 to 3, and a pharmacologically acceptable carrier.

17. A use of a vaccine composition as defined in Claim 13 for immunizing an individual against infection from hepatitis E virus.

18. A method for determining the presence or absence of HEV antibodies in a biological test sample, comprising:

- providing a purified and isolated peptide, pE2, comprising an amino acid sequence represented by SEQ ID NO: 2, or a homologous sequence, fragment or analog thereof having antigenic properties similar to the pE2 peptide;

- contacting the biological test sample suspected of containing HEV antibodies with the pE2 peptide;

- incubating the resultant mixture under conditions sufficient to allow the formation of an immunological (antibody-antigen) complex; and

- examining the mixture for the presence of such an immunological complex, whereby the formation of the complex indicates the presence of HEV antibodies in the test sample.

19. A method according to Claim 18, characterized in that the biological test sample is human blood, serum or plasma.

20. A method according to Claim 18 or 19, characterized in that the presence of the immunological complex is determined following incubation with an indicator reagent under conditions permitting a reaction to occur.

21. A method according to Claim 20, characterized in that the indicator reagent is a mammalian anti-human immunoglobulin attached to an enzyme which reacts with a substrate to form a colored product.

22. A diagnostic test kit for the detection of antibodies to hepatitis E virus (HEV), comprising:

- a purified and isolated peptide, pE2, comprising an amino acid sequence identified by SEQ ID NO: 2, or a homologous sequence, fragment or analog thereof having antigenic properties similar to the pE2 peptide; and

- an indicator reagent capable of detecting an immunological (antigen-antibody) complex which contains the pE2 peptide.

23. A diagnostic test kit according to Claim 22, which further comprises:

- control standards; and

- a specimen diluent and/or washing buffer.

24. A diagnostic test kit according to Claim 22 or 23, characterized in that the peptide, pE2, is immobilized to a solid support.

25. A diagnostic test kit according to Claim 24, characterized in that the solid support is the well of a titration microplate.

26. A method for detecting hepatitis E virus (HEV) virus particle, in a biological test sample, comprising:

- providing the purified anti-pE2 antibody, as defined in Claim 15;
- contacting and incubating the anti-pE2 antibody with the biological test sample under conditions which allow the formation of a complex containing the anti-E2 antibody and HEV virus particle; and
- examining the mixture for the presence of such a complex, whereby the formation of the complex indicates the presence of HEV virus particle, in the test sample.

27. A method according to Claim 26, characterized in that the presence of the HEV virus particle captured by the anti-pE2 antibody is determined by extracting viral RNA and applying reverse transcriptase polymerase chain reaction (RT-PCR) thereon.

28. A diagnostic reagent for detecting hepatitis E virus (HEV) analyte in a biological test sample comprising the purified anti-pE2 antibody, as defined in Claim 15.

29. The use of a purified anti-pE2 antibody, as defined in Claim 15, as a diagnostic reagent for the detection of hepatitis E virus (HEV) analyte in a biological test sample.

30. A diagnostic test kit for detecting hepatitis E virus (HEV) analyte in a biological test sample, comprising the diagnostic reagent as defined in Claim 28.

31. A diagnostic test kit according to Claim 30, characterized in that the purified anti-pE2 antibody is immobilized to a solid support.

32. An antigenic determinant, characterized in that the antigenic determinant is capable of being immunologically recognized by HEV antibodies present in serum of a patient afflicted with hepatitis E virus (HEV) and by anti-pE2 antibodies, as defined in Claim 15.

33. An diagnostic reagent for determining the presence or absence of hepatitis E virus (HEV) antibodies in a biological test sample, characterized in that the diagnostic reagent comprises a protein, polypeptide or a peptide having in common with the pE2 peptide, as defined in Claim 1, one or more antigenic determinants capable of being recognized by antibodies raised against the pE2 peptide.